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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,715	07/20/2001	Brian J. Cox	18455.11	1492
31278	7590	05/31/2005	EXAMINER	
STRADLING YOCCA CARLSON & RAUTH SUITE 1600 660 NEWPORT CENTER DRIVE P.O. BOX 7680 NEWPORT BEACH, CA 92660			PANTUCK, BRADFORD C	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,715

Applicant(s)

COX, BRIAN J.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 20, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-47, 54-56, 59-100 is/are pending in the application.
- 4a) Of the above claim(s) 59, 70-75, 78-80 and 86 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 69 and 81-85 is/are allowed.
- 6) ☒ Claim(s) 44-47, 54-56, 60-68, 76, 77 and 87-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 31, 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04-20-2005</u> | 6) <input checked="" type="checkbox"/> Other: <u>Attachment A</u> |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “attachment device” including “barbs, hooks, needles, spurs, and adhesive areas” must be shown or the feature(s) canceled from the claim(s) [see claims 62 and 63]. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 44-47, 54-56, 60, 61, 67, 68, 76, 77, 87-94 are rejected under 35

U.S.C. 102(e) as being U.S. Patent No. 6,398,808 to Palasis. Palasis discloses the stent 100 shown in Fig. 1A, including fenestrations between struts 110. Palasis discloses applying a coating 130 to “at least part of the stent structure 110” [column 3 line 64 to column 4 line 65]. Said coating will *necessarily at least partially fill the fenestrations* between the struts 110. The coating (in one embodiment) is a hydrogel [column 2 line 64; column 7 lines 12-13], which inherently contains all of the characteristics of the hydrogel set forth by Applicant.

Regarding the limitation that the stent is expandable from a diameter D to a diameter D', Palasis teaches a “stent structure 110 having struts 120 of any suitable metallic or polymeric material, *as is known in the art*” [column 3 line 65 to column 4 line 2] (emphasis added by Examiner). Such stents are well known in the art to be expandable.

2. Claims 95-100 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,613,074 B1 to Mitelberg et al. Mitelberg discloses an apparatus for treating vascular aneurysms including six fenestrations, i.e. windows or openings, as labeled in Attachment A. The body of the stent is cylindrical and blood flows through the internal lumen. A reactive material (hydrogel) [column 5, lines 32-33] is applied to fenestrations 2-4 ("not all"), as shown in Figure 6. Hydrogels react in the presence of liquids, in this case blood. Hydrogel (38) "is intended to significantly reduce...the flow into the aneurysm" [column 5, lines 26-29]. In other words, applying a hydrogel to the fenestrations increases the resistance of blood flow through the fenestrations (compared to naked frame shown in Fig. 5), but *still allows some blood to flow into the aneurysm*. Mitelberg's stent is radially expandable to be the size of the interior lumen of the blood vessel [Column 2, lines 38-39]. Mitelberg's hydrogel expands with the stimulus of being exposed to a liquid (blood).
3. Regarding Claim 96, because Mitelberg's reactive material (38) is a hydrogel, just like the Applicant's, it will react in the same ways to the blood (including the pH of the blood), and other internal fluids and proteins of the vasculature. *The normal pH of blood is between 7.35 and 7.45* [MedicineNet.com article], and because Mitelberg's invention is meant to be applied to the inside of blood vessels, the reaction (swelling) will occur at a pH of about 7.4.
4. Regarding Claim 97, Mitelberg's reactive material (hydrogel) *will* obtain a reacted (expanded) volume V' in the presence of a physiological pH of about 7.4.

5. Regarding Claims 98-100, Mittelberg's coating (in one embodiment) is made out of hydrogel, which inherently contains all of the characteristics of the hydrogel set forth by Applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,808 by Palasis. Palasis discloses a stent, but fails to disclose a barb, hook, needle, spur, or adhesive means to attach the stent to the blood vessel. However, such means are extremely well known in the art of stents and are often placed at the ends of the stent to make sure that the stent stays in position.
7. Claims 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,808 by Palasis in view of U.S. Patent No. 6,613,074 to Mittelburg et al. Palasis discloses "stent structure 110 having struts 120 of any suitable metallic or polymeric material, *as is known in the art* [column 3 line 65 to column 4 line 2] (emphasis added by Examiner). However, Palasis does not disclose particular metals or particular polymers, *since these materials are well known in the art*. Mittelburg teaches making a stent out of radio-opaque materials [Column 2, lines 56-58] so that they stent can be used with modern fluoroscopy viewing. Regarding Claim 64,

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Mitelberg's stent (12/30) [Figures 5/6] is made out of titanium [Column 4, lines 60-67]. Mitelberg's support member can be made out of all of the materials disclosed as the applicant's support member, and will therefore have the same properties as the Applicant's. For that reason, although not specifically disclosed as "echo-genic," Mitelberg's support member will have internal echoes, just like the Applicant's. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to choose the exemplary materials taught by Mitelberg representative of the generic materials disclosed by Palasis, as an obvious matter of design choice.

Allowable Subject Matter

8. Claims 69 and 81-85 are allowed.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory

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period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

10. Applicant's arguments, see "REMARKS", filed April 20, 2005, with respect to the rejection(s) of claim(s) 44-47, 51-56, 60-68, 76, 77, 81-85 under 35 USC § 102 (U.S. Patent No. 6,613,074 B1 to Mitelberg et al.) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of U.S. Patent No. 6,398,808 to Palasis.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C. Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
May 23, 2005


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
5/26/05

Fenestrations
①②③④⑤⑥

FIG. 5

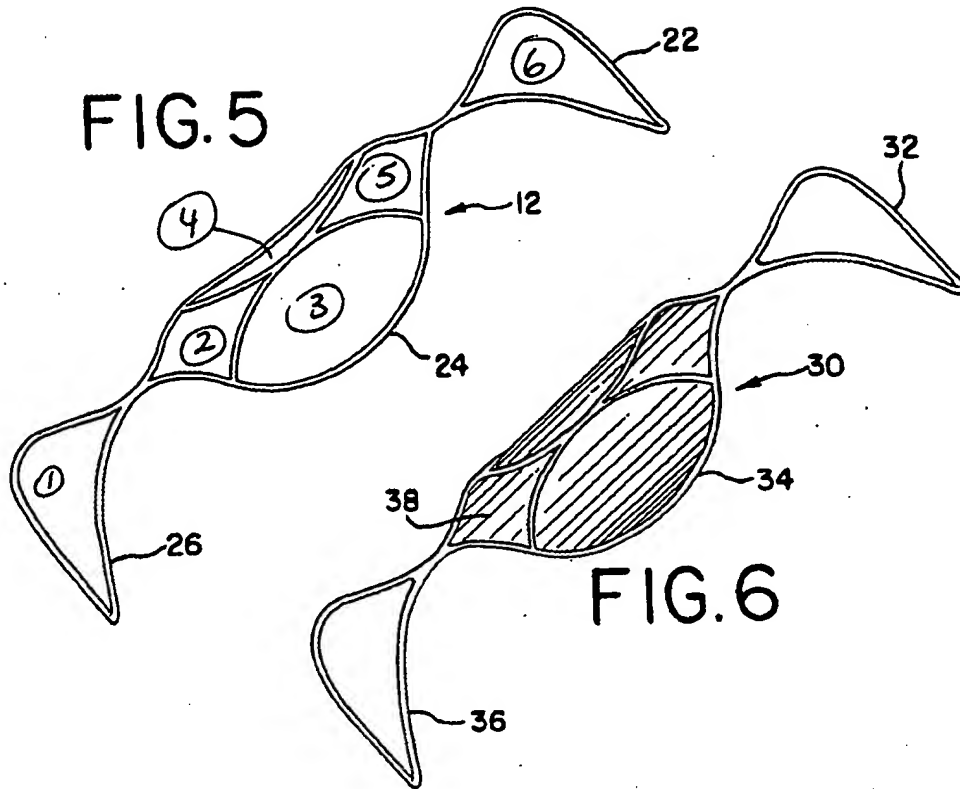


FIG. 5a

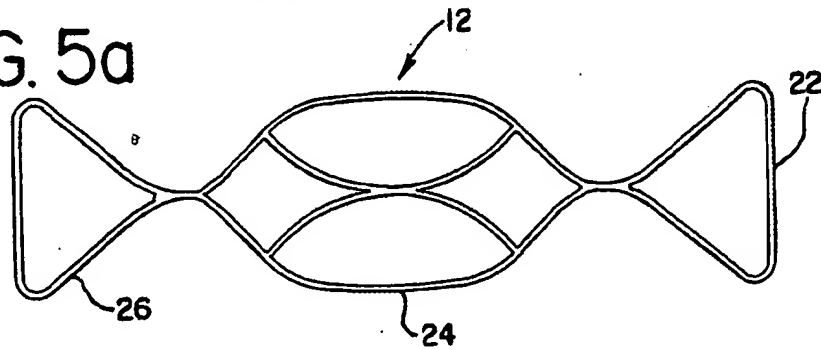


FIG. 5b

